

APR - 7 2011

510(k) Summary

Submitted By: CoAlign Innovations
150 North Hill Drive, Suite 1
Brisbane, CA 94005

**Establishment
Registration Number:** 10030843

**Contact Person:
(Submission Prepared by)** Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Date Prepared: January 27, 2011

Device Trade Name: AccuLIF Cage

Manufacturer: CoAlign Innovations, Inc.
150 North Hill Drive, Suite 1
Brisbane, CA 94005

Common Name: Spinal intervertebral body fixation orthosis

Classification: 21 CFR §888.3080

Class: II

Product Code: MAX, MQP

Device Description:

The AccuLIF Cage acts as a spacer to maintain proper intervertebral and vertebral body spacing and angulation following discectomy or partial corpectomy. The AccuLIF Cage is manufactured from Ti6Al4V and stainless steel. The AccuLIF Cage comes in 6 to 9mm, 8 to 12mm and 10 to 16mm sizes.

Indications For Use:

Intervertebral Body Fusion Device: The CoAlign Innovations AccuLIF Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I

spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The device is to be used with supplemental fixation.

Vertebral Body Replacement: When used as a vertebral body replacement, the CoAlign Innovations AccuLIF Cage is intended for partial vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable portion of a vertebral body, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

The CoAlign Innovations AccuLIF Cage is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The device is always to be used with supplemental internal spinal fixation. Additionally, the device may be used with bone graft.

Identification of Predicates

- SEC IBF Cage (K093669)

Summary of Technological Characteristics

AccuLIF Cages are expandable spacers made from Titanium-6AL-4V ELI alloy that conforms to ASTM F136. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Device footprint
- Bone graft port
- Expansion mechanism
- Structural support geometry

Discussion of Testing:

The following non-clinical tests were conducted:

- Dynamic compression testing, conducted in accordance with ASTM F2077-03
- Dynamic shear testing, conducted in accordance with ASTM F2077-03
- Dynamic torsion testing, conducted in accordance with ASTM F2077-03
- Static compression testing, conducted in accordance with ASTM F2077-03
- Static shear testing, conducted in accordance with ASTM F2077-03

- Static torsion testing, conducted in accordance with ASTM F2077-03
- Wear assessments following dynamic compression, dynamic shear, and dynamic torsion testing
- Surgical technique validation, conducted in the same manner as the predicate surgical technique validation.

Conclusions:

The subject and predicate devices share the same indications for use, design, function, and materials of manufacture. The non-clinical test results demonstrate that any minor differences do not impact device performance as compared to the predicates. The AccuLIF Cage was shown to be substantially equivalent to the SEC IBF Cage (K093669).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

CoAlign Innovations, Inc.
% Musculoskeletal Clinical Regulatory Advisors, LLC
Mr. Justin Eggleton
1331 H Street, Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K110270

APR - 7 2011

Trade/Device Name: AccuLIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: March 8, 2011
Received: March 10, 2011

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

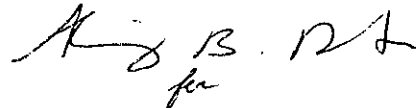
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K110270

Device Name: AccuLIF Cage

Intervertebral Body Fusion Device: The CoAlign Innovations AccuLIF Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The device is to be used with supplemental fixation.

Vertebral Body Replacement: When used as a vertebral body replacement, CoAlign Innovations AccuLIF Cage is intended for partial vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable portion of a vertebral body, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

The CoAlign Innovations AccuLIF Cage is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The device is always to be used with supplemental internal spinal fixation. Additionally, the device may be used with bone graft.


Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110270